

AGENDA
CIRCULATORY SYSTEM DEVICES PANEL

January 13, 2005

Hilton Gaithersburg Washington D.C./North, Salons A, B & C, 620 Perry Parkway, Gaithersburg, MD.

9:00 – 5:00	PMA Discussion and Recommendations
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9:00 a.m.	Call to Order	William H. Maisel, M.D., M.P.H. Acting Chairperson
9:05 – 9:20 a.m.	FDA Presentation - Critical Path Initiative Dr. Binita Ashar; Acting Clinical Director; CDRH	
9:20 – 9:35 a.m.	FDA Presentation – Panel Update Megan Moynahan; Branch Chief; Pacing, Defibrillator Leads Branch; CDRH	
9:35 – 10:05 a.m.	*Open Public Session*	
10:05 – 11:05 a.m.	Sponsor Presentation: W.L. Gore & Associates, Inc. P040043: Gore TAG Thoracic Endoprosthesis	
11:05 – 11:20 a.m.	Questions and Answers	
11:20 – 11:30 a.m.	Break	
11:30 – 12:30 p.m.	FDA Presentation	
12:30 – 12:45 p.m.	Questions and Answers	
12:45 p.m.	Adjourn – Break for Lunch	
1:45 p.m.	Call to Order	
1:45 – 3:45 p.m.	Open Committee Discussion	William H. Maisel, M.D.
3:45 – 4:00 p.m.	Break	
4:00 – 5:00 p.m.	*Open Public Session* FDA Comments Sponsor Comments Recommendations & Vote	William H. Maisel, M.D.
5:00 p.m.	Adjourn	

OPEN PUBLIC HEARINGS*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Ms. Wood will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Maisel will recognize unscheduled speakers as time allows.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.